TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Brand Hormonal Contraceptives with Therapeutically Equivalent Generic

Effective: December 10, 2019

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RxUM

These pharmacy medical necessity guidelines apply to the following:	Fax Numbers:
Commercial Products ☒ Tufts Health Plan Commercial products – large group plans ☒ Tufts Health Plan Commercial products – small group and individual plans ☒ Tufts Health Freedom Plan products – large group plans ☒ Tufts Health Freedom Plan products – small group plans • CareLink[SM] – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization **Tufts Health Public Plans Products** ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans ☐ Tufts Health RITogether – A Rhode Island Medicaid Plan	RXUM: 617.673.0988 MM: 888.415.9055 PRECERT: 617.972.9409

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Intent: Allow member to receive a brand hormonal contraceptive medication with available therapeutically equivalent generic alternative when the branded formulation is determined to be medically appropriate.

The Medical Necessity Guidelines apply to brand self-administered hormonal contraceptives, including oral contraceptives, patches and rings, with available therapeutically equivalent generic, that by law require a prescription and are covered in full under the pharmacy benefit.

COVERAGE GUIDELINES

The plan may authorize coverage of a brand hormonal contraceptive with available therapeutically equivalent generic, when there is clinical documentation from the requesting physician that the generic drug would not be medically appropriate, such as by:

1. The Member has had a treatment failure of 2 or more formulary alternative medications including the A-rated generic

OR

2. Member has an allergy to an ingredient in the A-rated generic product that is not contained in the brand-name product

OR

3. Clinical justification that a change to the generic formulation would result in instability of the medical condition

OR

4. The request for the brand-name product is due to a drug shortage

OR

5. The requesting physician provides clinical rationale that the requested brand drug is medically necessary for the patient

LIMITATIONS

- The brand hormonal contraceptives that do not have an FDA approved therapeutically equivalent generic alternative are not subject to this Medical Necessity Guidelines
- This Medical Necessity Guidelines do not apply to contraceptive agents that require administration by a health care professional (e.g. intramuscular injections, intrauterine devices), over-the-counter contraceptives, and non-hormonal contraceptives (e.g. diaphragms, condoms)
- This Medical Necessity Guidelines does not apply to members of "grandfathered" plans and certain religious group employers that are exempt from the requirement to cover contraceptive services

CODES

None

REFERENCES

1. Orange book: Approved drug products with therapeutic equivalence evaluations. 38th edition. (2018). Rockville, MD.: U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs.
2. American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 375: Brand versus generic oral contraceptives. Obstet Gynecol. 2007 Aug; 110 :447-8.

APPROVAL HISTORY

October 16, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 10, 2019: No Changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services